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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/090,280 | 03/05/2002 | Marie Rosier | 03806.0543-00 | 6663 |

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| EXAMINER | |
|---|---|
| STRZELECKA, TERESA E | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1637 | 7 |

DATE MAILED: 06/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/090,280 | ROSIER ET AL. | |
| | Examiner | Art Unit | |
| | Teresa E Strzelecka | 1637 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-40 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) 9 is/are objected to.

8)☒ Claim(s) 1-8, 10-40 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Claim Objections*

1. Claim 9 is objected to because it depends from claim 8, and in part b) it depends from claims 6-8. Accordingly, the claim has not been further treated on the merits.

### *Election/Restrictions*

2. Each Group detailed below reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid or nucleic acid sequences, the Applicants must further elect a single amino acid or a single nucleic acid sequence (See MPEP 803.04).

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 10-20, 30, 31, drawn to an isolated nucleic acid comprising any one of SEQ ID NO: 1-32, a kit for amplifying the nucleic acid, and a method of amplifying the nucleic acid, classified in class 536, subclass 23.1, for example.

II. Claims 21-24 and 40, drawn to an isolated nucleic acid encoding a polypeptide comprising an amino acid sequence of SEQ ID NO: 33 or 34, classified in class 536, subclass 23.5, for example.

III. Claims 25, 35, drawn to an isolated polypeptide and a composition comprising the polypeptide, classified in class 530, subclass 350, for example.

IV. Claims 26, 27 and 29, drawn to an antibody and a kit comprising the antibody, classified in class 530, subclass 387.1, for example.

V. Claim 28, drawn to a method of detecting a polypeptide using an antibody, classified in class 435, subclass 7.1, for example.

VI. Claim 32, drawn to a method of treating and/or preventing paroxysmal kinesigenic choreoathetosis by administration of a nucleic acid, classified in class 514, subclass 44, for example.

VII. Claim 33, drawn to a method of treating and/or preventing paroxysmal kinesigenic choreoathetosis by administration of a vector, classified in class 424, subclass 93.1, for example.

VIII. Claim 34, drawn to a method of treating and/or preventing paroxysmal kinesigenic choreoathetosis by administration of a polypeptide, classified in class 514, subclass 2, for example.

IX. Claim 36, drawn to a method of identifying active ingredients for the treatment or prevention of paroxysmal kinesigenic choreoathetosis by using an isolated polypeptide, classified in class 435, subclass 7.1, for example.

X. Claim 37, drawn to a method of identifying active ingredients for the treatment or prevention of paroxysmal kinesigenic choreoathetosis by using a recombinant host cell, classified in class 435, subclass 29, for example.

XI. Claim 38, drawn to a method of identifying an agonist or antagonist of the polypeptide by incubation of the polypeptide enclosed in a membrane vesicle with a candidate compound, classified in class 435, subclass 7.1.

XII. Claim 39, drawn to a method of identifying an agonist or antagonist of the polypeptide by incubation of a cell encoding the polypeptide with a candidate compound, classified in class 435, subclass 7.2.

The inventions are distinct, each from the other because of the following reasons:

4. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are nucleic acids with different sequences.

5. Inventions (I, II) and III are separate and distinct because the inventions are directed to different chemical types regarding the critical limitations therein. For Group III the critical feature is a polypeptide whereas for Groups I and II the critical feature is a polynucleotide. It is acknowledged that various processing steps may cause a polypeptide of Group III to be directed as to its synthesis by a polynucleotides of Group I and II, however, the completely separate chemical types of the inventions of Groups (I and II) and III supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examiner together, as compared to being searched separately. Also, it is pointed out that processing that may connect two groups does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

6. Inventions (I, II) and IV are separate and distinct, as the claims of Inventions I and II are drawn to polynucleotides, while the claims of Group IV are drawn to an antibody. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention IV would require searching in areas unrelated to polynucleotides, and as such, would require an undue burden on the examiner if not restricted.

7. Inventions (I, II) and (V, VII-XII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or

they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the polynucleotides of Groups I and II are not required for the methods of Groups V, VII-XII.

8. Inventions (I, II) and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides can be used in a different method, such as expression of proteins which they encode, rather than in the method of Group VI.

9. Inventions III and IV are separate and distinct, as the claims of Invention III are drawn to polypeptides, while the claims of Group XII are drawn to antibodies. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention IV would require searching in areas unrelated to polypeptides, and as such, would require an undue burden on the examiner if not restricted.

10. Inventions III and (V-VII, X and XII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the polypeptides of Groups III is not required for the methods of Groups V-VII, X and XII.

11. Inventions III and (VIII, IX and XI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product

(MPEP § 806.05(h)). In the instant case the polypeptides of Group III can be used in an entirely different process, such as production of antibodies, rather than in the methods of Groups VIII, IX and XI.

12. Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group IV can be used in an entirely different process, such as purification of a polypeptide, rather than in the method of Group V.

13. Inventions IV and (VI-XII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the antibodies of Groups IV are not required for the methods of Groups V-XII.

14. Inventions VI-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to methods which have different method steps, starting materials and goals.

15. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

16. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

17. A telephone call was made to Elizabeth Doherty on June 2, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

18. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

June 10, 2003

Teresa Strzelecka, Ph.D.

Patent Examiner